DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
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May 6, 2016

Olympus Winter & Ibe GmbH
% Mr. Graham Baillie
Manager, Regulatory Affairs
Gyrus ACMI, Inc.
136 Turnpike Road
Southborough, Massachusetts 01772

Re: K160053
Trade/Device Name: Monopolar Single-use HF Cable
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical Cutting And Coagulation Device And Accessories
Regulatory Class: Class II
Product Code: GEI
Dated: April 20, 2016
Received: April 21, 2016

Dear Mr. Baillie:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-

related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Jennifer R. Stevenson -A

For Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K160053

Device Name
Monopolar single-use HF cable

Indications for Use *(Describe)*
HF cable for electrotherapeutical use in endoscopic procedures in conjunction with compatible active accessories and compatible electrosurgical units.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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Monopolar single-use HF cable

510(k) PREMARKET NOTIFICATION

SECTION 2 – 510k Summary

Olympus Winter & Ibe GmbH
Hamburg, Germany

510(k) Summary
December 07, 2015

1. General Information

Manufacturer:
Olympus Winter & Ibe GmbH
Kuehnstr. 61
22045 Hamburg
Germany

Establishment Registration Number: 9610773

Official Correspondent:
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Phone: 508.804.2738
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Establishment Registration No: 3003790304

2. Device Identification

Common Name:	Electrosurgical, Cutting & Coagulation & Accessories
Regulation Number:	878.4400
Regulation Description:	Electrosurgical cutting and coagulation device and accessories
Device Class:	II
Product Code:	GEI
Review Panel:	General & Plastic Surgery
Proprietary/Trade Name:	Monopolar single-use HF cable

3. Predicate Devices

510(k) No.	Name	Predicate Model No.	Product code / Reg No.
K944200/1	HF-cable, monopolar	A0358	GCJ / 876.1500
K890328	Disposable Active Cord	DAC	FAS / 876.4300 GEI / 878.4400 HIH / 884.1690

The predicates have not been subject to a design-related recall.

No reference devices were used in this submission.

4. Product Description

The Olympus monopolar single-use HF cable that is subject to this submission connects a compatible electrosurgical generator with the working element of a resectoscope for the application of monopolar HF current during endoscopic procedures.

The HF cable is delivered in sterile condition and is intended for single use only.

The monopolar single-use HF cable consists of a proximal plug connecting to the HF generator, an insulated cord and a distal plug connecting to the working element of the resectoscope.

5. Indications for Use

"HF cable for electrotherapeutical use in endoscopic procedures in conjunction with compatible active accessories and compatible electrosurgical units."

This intended use is essentially the same intended use as that of the predicate devices.

6. Comparison of Technological characteristics

The subject and predicate devices are based on the same technological principle with similar elements:

- HF cable consisting of a proximal plug connecting to the HF generator, an insulated cord and a distal plug connecting to an active instrument
- Predicate and subject devices are designed for use with monopolar current
- Similar outer dimensions
- Design changes of the HF cable are minor and do not negatively impact safety or effectiveness of the subject devices
- There are no patient-contacting materials in predicates and subject device

While one of the predicate devices (A0538) is reusable and can be reprocessed, the other predicate (DAC) and the subject device are provided in sterile condition and are

intended for single-use only. Accordingly, outside materials differ to suit differing durability needs. Also, material selection of the single-use predicate and subject device differ; however, durability of the new materials has been tested successfully.

7. Performance Data

The following performance data was provided in support of the substantial equivalence determination. All standards applied are FDA recognized international standards.

Electrical safety and electromagnetic compatibility (EMC)
Electrical Safety was tested according to

AAMI/ANSI ES 60601-1:2005 + A1:2012, C1:2009 and A2:2010	Medical Electrical Equipment - Part 1.1 General requirements for safety and essential performance.
AAMI/ANSI/IEC 60601-2-2 2009	Medical Electrical Equipment - Part 2-2: Particular Requirements for the Basic Safety And Essential Performance of High Frequency Surgical Equipment and High Frequency Surgical Accessories
IEC 60601-2-18:2009	Medical electrical equipment - Part 2-18: Medical Electrical Equipment - Part 2-18: Particular requirements for the basic safety and essential performance of endoscopic equipment.
IEC 60601-1-2:2007	Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests

Clinical Evaluation
Clinical and animal studies were not necessary.
A clinical evaluation has been conducted containing a comprehensive literature review.

Software
Not applicable as the HF cable does not contain any software.

Performance Testing Bench
Conducted tests included the following tests:

- Insertion & Retraction Force tests of connectors
- Cable marking durability test
- Surface temperature measurement test
- Cable insulation HF and Mains Dielectric Strength test
- Cable anchorage test
- Fluid ingress test
- Continuity test
- Cable tensile strength test
- Connector grip test
- Output power measurement
- Transport testing

8. Sterilization and Shelf Life

Sterilization is performed according to ISO 11135 and packaging conforms with AAMI ANSI ISO 11607-1:2006. The EtO sterilization cycle has been validated.

A sterility assurance level (SAL) of 10^{-6} was reached during validation and will be used for routine sterilization in compliance with regulations in force for sterile medical devices.

The EtO residuals are within the limits after tunnel degassing time.

Shelf Life testing supports a shelf life of 1 year for the monopolar single-use HF cable.

9. Conclusion

The performance data support the safety of the device and demonstrate that the subject device complies with the intended use as specified.

In summary, we believe the monopolar single-use HF cable is substantially equivalent with the predicate devices with respect to the general design approach, function, and the intended use. The HF cable raises no new concerns of safety or effectiveness when compared to the predicate devices.